REMARKS

Applicants respectfully request reconsideration of this application in view of the following remarks.

I. Status of the Claims

Claims 1-21 remain pending in this application, with claim 2 being withdrawn from consideration. No claims presently are being amended, canceled or added.

II. The Claims Merit Priority to U.S. Patent 5,079,262, filed July 28, 1989

The Office asserted that the pending claims do not merit priority to U.S. Patent 5,079,262, filed July 28, 1989. More particularly, the Office stated that the '262 patent describes treating only hyperproliferative skin lesions, not "the entire genus of non-malignant skin lesions," and describes only using the wavelength of light between 350-640 nanometers, not wavelengths of light up to 700 nm. Accordingly, the Office only granted priority to U.S. application 09/293,834, filed April 19, 1999. Applicants respectfully disagree with the Office's conclusions regarding priority.

Contrary to the Office's assessment, the '262 patent describes treating "the entire genus of non-malignant skin lesions." From its very beginning, the '262 patent specification states that the invention relates to "treatment of certain tissue abnormalities (both cancerous and non-malignant)," with no requirement that the abnormalities be hyperproliferative conditions. (Column 1, lines 7-9). The '262 patent specification explains that "[c]ertain types of cells and tissues can synthesize relatively large quantities of PpIX" and "accumulate such a large excess of PpIX that they become both fluorescent and photosensitive." (Column 4, lines 17-19 and 26-28). It further explains that skin, in particular, synthesizes PpIX in situ. (Column 4, lines 28-30). Due to the ability of skin to synthesize PpIX in situ, the patent contemplates treating both "carcinomas and other lesions of the skin," without stating a requirement for the lesions to be hyperproliferative. (Column 4, lines 40-44). Exemplary non-malignant skin lesions identified by the patent are genital warts and psoriasis. (Column 4, lines 44-45).

Also contrary to the Office's assessment, the '262 patent describes using wavelengths of light up to 700 nanometers. The patent states that after lesions accumulate protoporphyrin IX, they should be exposed "to light having a wavelength within the photoactivating action spectrum of said PpIX to thereby induce photoactivation" in the lesions. (Column 3, line 67 – column 4, line 2). In that regard, the patent states that "[t]he wavelength of the photoactivating light is of some importance, as it has been shown that between 1 and 10 percent of incident red light (600-700 nm) can pass through a slab of human tissue 1 cm thick." (Column 4, lines 60-63). It further states that PpIX strongly absorbs red light. (Column 4, lines 67-68). This is a clear representation to skilled artisans that the invention embraces using wavelengths of light more than 600 nanometers and up to 700 nanometers.

All the intervening links in this application's priority chain similarly support the pending claims. U.S. Patent 5,211,938 is a continuation of the '262 patent; therefore, the two patents contain the same disclosure.

U.S. Patent 5,234,940 is a continuation in part of the '938 patent and also begins with a statement that the invention relates to "treatment of certain tissue abnormalities (both cancerous and non-malignant)," with no requirement that the abnormalities be hyperproliferative conditions. (Column 1, lines 15-18). The '940 patent specification explains that "[c]ertain types of cells and tissues can synthesize relatively large quantities of PpIX" and "accumulate such a large excess of PpIX that they become both fluorescent and photosensitive." (Column 4, lines 37-39 and 46-48). It further explains that skin, in particular, synthesizes PpIX in situ. (Column 4, lines 48-50). Due to the ability of skin to synthesize PpIX in situ, the patent contemplates treating both "carcinomas and other lesions of the skin," without stating a requirement for the lesions to be hyperproliferative. (Column 4, lines 60-64). Exemplary non-malignant skin lesions identified by the patent are genital warts and psoriasis. (Column 5, lines 23-24).

The '940 patent also describes using wavelengths of light up to 700 nanometers. The patent states that after lesions accumulate protoporphyrin IX, they should be exposed "to light of photoactivating wavelengths." (Abstract). In that regard, the patent states that "[t]he wavelength of the photoactivating light is of some importance, as it has been shown that

between 1 and 10 percent of incident red light (600-700 nm) can pass through a slab of human tissue 1 cm thick." (Column 6, lines 5-8). It further states that PpIX strongly absorbs red light. (Column 6, lines 12-13). This is a clear representation to skilled artisans that the invention embraces using wavelengths of light more than 600 nanometers and up to 700 nanometers.

U.S. Patent 5,422,093 is a continuation in part of the '940 patent and also begins with a statement that the invention relates to "treatment of certain tissue abnormalities (both cancerous and non-malignant)," with no requirement that the abnormalities be hyperproliferative conditions. (Column 1, lines 18-20). The '093 patent specification explains that "[c]ertain types of cells and tissues can synthesize relatively large quantities of PpIX" and "accumulate such a large excess of PpIX that they become both fluorescent and photosensitive." (Column 5, lines 11-14 and 20-22). It further explains that skin, in particular, synthesizes PpIX in situ. (Column 5, lines 22-24). Due to the ability of skin to synthesize PpIX in situ, the patent contemplates treating both "carcinomas and other lesions of the skin," without stating a requirement for the lesions to be hyperproliferative. (Column 5, lines 37-41). Exemplary non-malignant skin lesions identified by the patent are genital warts and psoriasis. (Column 6, lines 1-2).

The '093 patent also describes using wavelengths of light up to 700 nanometers. The patent states that after lesions accumulate protoporphyrin IX, they should be exposed "to light of photoactivating wavelengths." (Abstract). In that regard, the patent states that "[t]he wavelength of the photoactivating light is of some importance, as it has been shown that between 1 and 10 percent of incident red light (600-700 nm) can pass through a slab of human tissue 1 cm thick." (Column 6, lines 52-55). It further states that PpIX strongly absorbs red light. (Column 6, lines 59-60). This is a clear representation to skilled artisans that the invention embraces using wavelengths of light more than 600 nanometers and up to 700 nanometers.

The Office already has acknowledged support in U.S. application 09/293,835, filed April 19, 1999, which is a continuation in part of the '093 patent and in U.S. Patent 6,710,066, filed March 26, 2001, by granting priority to the '835 application.

Because the '262 patent and all the intervening priority documents support the scope of the pending claims, applicants respectfully request that the Office award this application benefit of priority to the '262 patent.

III. Double Patenting

The Office rejected claims 1 and 3-21 for alleged obviousness-type double patenting over claims 1-12 of U.S. Patent 6,710,066, claims 1-12 of U.S. Patent 5,955,490 and claims 1-2 of U.S. Patent No. 5,211,938.

Although Applicants disagree with the rejection, they intend to file a terminal disclaimer, once the claims in this application are otherwise deemed allowable, that will obviate the rejection.

IV. The Claims Are Patentable over U.S. Patent 5,705,518

The Office asserted that U.S. Patent 5,705,518 ("Richter") anticipated claims 1 and 3-21. Applicants traverse the rejection.

Richter is not prior art. Richter bears a publication date of January 6, 1998 and an alleged earliest priority date of November 20, 1992. Both those dates are after the present application's July 28, 1989 priority date. Accordingly, Applicants respectfully request withdrawal of the anticipation rejection.

V. The Claims Are Patentable over U.S. Patent 4,977,177

The Office asserted that U.S. Patent 4,977,177 ("Bommer") anticipated claims 1, 6-16 and 18-21. Applicants traverse the rejection.

Bommer did not disclose compounds that are precursors of protoporphyrin IX, as required by claims 1 and 3-10; nor did Bommer disclose compounds that are not themselves photosensitizers but induce the synthesis of protoporphyrin IX *in vivo*, as required by claims 11-21.

Bommer is directed to compounds that are mono-, di- or polyamides of an amino monocarboxylic acid and a tetrapyrrole that contains an amino acid linkage. The Bommer compounds are pre-formed photosensitizers. They are photoactive before administration, at

the time of administration and after administration. Additionally, the Bommer compounds function entirely independently of the heme biosynthetic pathway. They do not induce an accumulation of protoporphyrin IX *in vivo*.

By contrast, compounds that are precursors of protoporphyrin IX and compounds that induce the synthesis of protoporphyrin IX *in vivo* depend on the heme biosynthetic pathway to cause an accumulation of protoporphyrin IX. The heme biosynthetic pathway is an enzymatically controlled metabolic process within cells, and its operation is specific to certain compounds, one if which is 5-ALA. None of the Bommer compounds act in this pathway; they therefore fall outside the scope of the pending claims.

Because Bommer did not teach the use of protoporphyrin IX precursors or compounds that induce the synthesis of protoporphyrin IX *in vivo*, the anticipation rejection is improper and Applicants respectfully request its withdrawal.

VI. The Claims Are Patentable over Divaris et al., Am. J. Path., 136(4): 891 (1990)

The Office asserted that Divaris et al., Am. J. Path., 136(4): 891 (1990) ("Divaris") anticipated claims 1 and 4-21. Applicants traverse the rejection.

Divaris is not prior art. Divaris bears a publication date of April 1990. That is after the present application's July 28, 1989 priority date. Accordingly, Applicants respectfully request withdrawal of the anticipation rejection.

VII. The Claims Are Patentable over the Combination of Richter and Bommer

The Office asserted that claims 1 and 3-21 are obvious over U.S. Patent 5,705,518 ("Richter") in view of U.S. Patent 4,97,177 ("Bommer"). Applicants traverse the rejection.

As explained above, Richter is not prior art. Richter bears a publication date of January 6, 1998 and an alleged earliest priority date of November 20, 1992. Both those dates are after the present application's July 28, 1989 priority date. Accordingly, Applicants respectfully request withdrawal of the obviousness rejection.

VIII. The Claims Are Patentable over U.S. Patent 5,093,349

The Office asserted that claims 1 and 3-21 are obvious over U.S. Patent 5,093,349 ("Pandey"). According to the Office, Pandey teaches using "dimers of deuteroporphyrins or hydrophobic esters thereof" in photodynamic therapy of skin tumors. Applicants traverse the rejection.

Pandey neither teaches nor suggests the claimed methods for treating non-malignant skin lesions. The claimed methods require administering "a precursor of protoporphyrin IX" or "an agent which is not a photosensitizer but induces the synthesis of protoporphyrin IX *in vivo*." The compounds described in Pandey do not meet either of those requirements. Indeed, Pandey explains at column 10, lines 56-65, that its described compounds "are [not] entered into any biological event" and "are not consumed or altered in exerting their biological effects." Because the compounds described by Pandey are not altered, they must already be photosensitizers at the time of administration. Likewise, because the compounds described by Pandey do not enter into any biological event and are not altered, they must not be precursors of protoporphyrin IX or induce the synthesis of protoporphyrin IX *in vivo*.

Pandey does not suggest using any compounds beyond those that it describes, and the Office did not identify any suggestion or motivation beyond Pandey to do so. Accordingly, the claimed invention is patentable over Pandey, and Applicants request withdrawal of the obviousness rejection.

IX. Concluding Remarks

This application is now in condition for allowance, and Applicants respectfully request favorable reconsideration of it.

If the Examiner believes that an interview would further advance prosecution, he or she is invited to contact the undersigned attorney by telephone.

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or

even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 2/13/06

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